unamended (or similar) claims in another application, for the purpose of furthering Applicants' business goals and expediting the patent application process in a manner consistent with the PTO's Patent Business Goals.

None of the amendments to the claims is related to the statutory requirements for patentability unless expressly stated so herein. Applicants reserve the right to prosecute the originally filed claims, as well as any other claims supported by the specification, in the future.

For the avoidance of doubt, Applicants note that, as set forth in the specification, Compound (I) may exist in one of several tautomeric forms, all of which are encompassed by the term Compound (I), as individual tautomeric forms or as mixtures thereof. Furthermore, Compound (I) contains a chiral atom, and therefore can exist in up to two stereoiosmeric forms, and the term Compound (I) encompasses all of these isomeric forms, whether as individual isomers or as mixtures of isomers, including racemates. See the specification at page 2, paragraphs 10 and 11. Accordingly, when reference is made to Compound (I), all such tautomeric and isomeric forms are encompassed.

Col 18
20-38

Additionally for the avoidance of doubt, as set for in the specification, when reference is made to scalar amounts, including mg amounts and % weight amounts, of "Compound (I) in a pharmaceutically acceptable form", the scalar amount referred to is made in respect of Compound (I) per se: for example, 2 mg of Compound (I) in the form of the maleate salt is that amount of maleate salt which contains 2 mg of Compound (I). See the specification, page 3, paragraph 5.

The comments in the Office Action are now addressed.

Election/Restriction

The Examiner has made the Restriction Requirement final and withdrawn the non-elected claims from consideration. In order to advance prosecution, Applicants are canceling the non-elected claims.

Rejection under 35 USC 102(e)

Claims 9-14 were rejected by the Examiner as being anticipated by Antonucci et al, US Patent No. 5,972,944A (hereinafter "Antonucci"). The Examiner asserts that Antonucci teaches rosiglitazone in a pharmaceutically acceptable carrier in unit dose form (citing Col. 10, lines 40-45 and Col. 18,

line 39 to Col. 19, line 60). The Examiner posits that the quantity of active component in a unit dose preparation may be varied or adjusted from 0.1 mg to 100 mg (citing Col. 19, lines 36-41), which is said to encompass the claimed 2-12 mg. The Examiner further states that the term "preparation" includes the formulation of the active compound with encapsulating material as a carrier providing a capsule in which the active with or without other carriers is surrounded by a carrier (citing Col. 18, lines 58-62), which is said by the Examiner to encompass claims 12-14. Applicants respectfully traverse the rejection.

Claims 9-11 and 13 have been canceled. Therefore, Applicants respond to the rejection as applied to claims 12 and 14 as amended, and new claims 23-54.

Present claim 12 is directed to a process for preparing a pharmaceutical composition of Compound (I) in a pharmaceutically acceptable form and a pharmaceutically acceptable carrier. The claimed process comprises a first step of (i) preparing a first composition comprising Compound (I) in a pharmaceutically acceptable form and a first pharmaceutically acceptable carrier. The claimed process comprises a further step of (ii) admixing the first composition with a second pharmaceutically acceptable carrier and thereafter formulating the composition produced into an administerable unit dosage form comprising 2 to 8 mg of Compound (I) in a pharmaceutically acceptable form. New independent claim 41 is directed to a process as in claim 12, except that the administerable unit dosage form formed in step (ii) comprises 1 to 8 mg of Compound (I) in a pharmaceutically acceptable form.

Antonucci is generally concerned with compounds which can be used to treat anovulation, hyperandrogenism and hirsutism. The disclosed methods of treating such conditions may comprise administering rosiglitazone (Col. 10, line 46 to Col. 12, line 3). Antonucci also discloses that the quantity of active component in a unit dose form preparation may be varied or adjusted from 0.1 mg to 100 mg, preferably 0.5 mg to 100 mg according to the particular application and the potency of the active component (Col. 19, lines 36-39). As noted by the Examiner, Antonucci discloses "solid form preparations" from the reference compounds, for example, at Col. 18, lines 58-62.

To anticipate a claim, a single source must contain all of the elements of the claims.[1] Missing elements may not be supplied by the knowledge of one skilled in the art or the disclosure of another reference.[2] Furthermore, the single source must disclose all of the claimed elements "arranged as in the claim".[3]

Applicants respectfully submit that Antonucci fails to teach each and every element of the present claims, and therefore does not anticipate the present claims.

That is, Applicants find no disclosure in Antonucci of a process for preparing a pharmaceutical composition comprising Compound (I) in a pharmaceutically acceptable form and a pharmaceutically acceptable carrier, which process comprises:

(i) preparing a first composition comprising Compound (I) in a pharmaceutically acceptable form and a first pharmaceutically acceptable carrier; and

(ii) admixing the first composition with a second pharmaceutically acceptable carrier and thereafter formulating the composition produced into an administerable unit dosage form comprising 1 to 8 mg of Compound (I) in a phamaceutically acceptable form (as required by present claim 41), or 2 to 8 mg of Compound (I) in pharmaceutically acceptable form (as required by present claim 12).

In particular, Applicants find no teaching or suggestion in Antonucci of a pharmaceutical composition prepared by a method comprising the steps of preparing a first composition of an active and a carrier, admixing the first composition with a second carrier, and thereafter formulating the composition produced into an administerable unit dosage form. Furthermore, Applicants find no teaching or suggestion in Antonucci of an administerable unit dosage

wet granulation is known technique

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[1] see, e.g., *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986).

[2] see, e.g., *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716, 223 U.S.P.Q. 1264, 1271 (Fed. Cir. 1984).

[3] see, e.g., *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989).

form comprising the specific compound, Compound (I) in a pharmaceutically acceptable form, in the specific amounts required by the present claims, no less which is prepared by a process comprising preparing a first composition comprising Compound (I) in a pharmaceutically acceptable form, and a first pharmaceutically acceptable carrier; and (ii) admixing the first composition with a second pharmaceutically acceptable carrier and thereafter formulating the composition produced into such administerable unit dosage forms.

While Antonucci discloses that the amount of active component in a unit dose form may be varied or adjusted from 0.1 mg (preferably 0.5 mg) to 100 mg, this teaching does not anticipate an administerable unit dosage form comprising 1 to 8 mg, or 2 to 8 mg, of active component, no less 1 to 8 mg or 2 to 8 mg of the specific compound, Compound (I) in a pharmaceutically acceptable form. Mere subsumption of Applicants' specific ranges of 1 to 8 mg or 2 to 8 mg (more particularly of Compound (I) in pharmaceutically acceptable form), in Antonucci's wide range of 0.1 to 100 mg, or 0.5 to 100 mg (of active component) is not literal identity and does not render the present claims anticipated.[4]

Moreover, Antonucci provides no basis to select the particular unit dosage active concentrations required by Applicants' claims, no less in conjunction with Compound (I) in a pharmaceutically acceptable form. Rather, the only particular treatments which Antonucci describes appear to be in the Examples 1 and 2. These Examples utilize a different compound, i.e., troglitazone, and Example 1 teaches a significantly different unit dosage, i.e., a unit dosage of 200 mg. These selections by Antonucci teach away from the present invention.

Applicants also respectfully traverse the Examiner's position that the "preparation" defined by Antonucci at Col. 18, lines 58-62, encompasses Applicants' claims 12-14 "wherein a first pharmaceutically acceptable carrier is mixed with the active and then admixing with a second pharmaceutically

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[4] see, e.g., *Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1572, 24 U.S.P.Q.2d 1321, 1332 (Fed. Cir. 1992)

acceptable carrier". At Col. 18, lines 58-62, Antonucci describes the term "preparation" as intended to include:

> the formulation of the active compound with encapsulating material as a carrier providing a capsule in which the active component with or without other carriers, is surrounded by a carrier, which is thus in association with it.

That is, Antonucci there describes a capsule, in which active material, with or without other carriers, is surrounded by a carrier which encapsulates the active and optional other carriers. According to its ordinary meaning and consistent with Antonucci's description, a capsule comprises a shell, often gelatinous, within which is packaged a material, such as a drug, vitamin or the like. While Antonucci's capsules may include a mixture of an active and carrier, Applicants find no teaching or suggestion of admixing a carrier with a pre-mixture of an active and carrier.

In view of the above remarks, Applicants respectfully submit that the present claims are not anticipated by Antonucci. Furthermore, Applicants find no teaching or suggestion in Antonucci of a first composition, as recited in certain of Applicants' claims, wherein the first composition is in granular form, or contains from 2-50 wt% or from 5-20 wt% of Compound (I) in pharmaceutically acceptable form, or which comprises the components recited in claims 27 and 46. In addition, Applicants find no teaching or suggestion in Antonucci to select a particular pharmaceutically acceptable form of Compound (I), such as a pharmaceutically acceptable salt of Compound (I), and in particular a maleate salt of Compound (I).

In view of all of the above, Applicants submit that the present claims are not anticipated by, and are patentable over, Antonucci.

Information Disclosure Statement

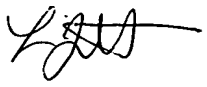
Applicants would like to inform the Examiner that an Information Disclosure Statement will be submitted shortly after this response, pending the receipt of references to be cited.

CONCLUSION

Applicants have addressed each of the issues raised by the Examiner and this is a complete response to the Office Action. Reconsideration is respectfully requested.

If any issues remain to be resolved in the present application, the Examiner is invited to contact the undersigned at the telephone number provided.

Respectfully submitted,



Loretta J. Henderson
Attorney for Applicants
Registration No. 37,347

GLAXOSMITHKLINE
Corporate Intellectual Property - UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939
Phone (610) 270-6897
Facsimile (610) 270-5090
P31824C1amendA.doc

Version to show changes made

(amendments to claims Dec 6, 2002)

12.(once amended) A process for preparing a pharmaceutical composition of ~~Compound (I)~~ 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione (hereinafter "Compound (I)") in a pharmaceutically acceptable form and a pharmaceutically acceptable carrier, which process comprises:

(i) preparing a first composition comprising Compound (I) in a pharmaceutically acceptable form and a first pharmaceutically acceptable carrier; and

(ii) admixing the first composition with a second pharmaceutically acceptable carrier and thereafter formulating the composition produced into an administerable unit dosage form comprising 2 to 8 mg of Compound (I) in a pharmaceutically acceptable form ~~to provide the required composition of Compound (I) and optionally thereafter formulating the composition produced into an administerable form~~.

14.(once amended) A process according to claim 12, wherein the ~~composition of Compound (I)~~ administerable unit dosage form is a tablet.